Ethical Standards in Sport and Exercise Science Research: 2020 Update

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Bibliography
DOI https://doi.org/10.1055/a-1015-3123
Published online: 15.10.2019
Int J Sports Med 2019; 40: 813–817

ISSN 0172-4622

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For publication in the International Journal of Sports Medicine (IJSM), studies must have been conducted in accordance with recognised ethical standards and national/international laws. At the very first stage of paper submission, authors are required to confirm that these standards and laws have been adhered to by reading this editorial. Authors who do not provide any information regarding ethical approval will have their manuscripts rejected before it enters the peer-review process, without any option to resubmit.

Research opportunities, methods and the contextual environment are continually evolving. While the four basic principles of biomedical ethics are, arguably, timeless [1], changes to data collection processes as well as research designs and settings bring changes to ethical considerations. In the original 2009 IJSM editorial [2], we described the ethical considerations embedded into national/international laws and provided specific guidance on the ethical issues which commonly arise in Sports Medicine research. In 2011, this information was updated to recognise the ethical principles of other professional associations and treaties when conducting research involving human participants [3]. Additional information was also provided on the use of Laboratory Animals in research, and on the links between sample size and research ethics. In the second update [4], published in 2014, we elaborated on the ethical issues relating to the investigation of doping agents; the use of animals for answering research questions that appear to be solely focussed on the enhancement of athletic performance; and sample size in the context of the burden to individual research participants. In 2016, we updated some of the guidelines to account for the changes made to the Declaration of Helsinki in 2013, covered the use of social media in research, provided guidance on how researchers can feed back their incidental and pertinent findings to research participants, covered some of the issues relating to studies involving children, and outlined the difference between a full and pilot study in terms of desired number of participants [5]. In the last update (2018), we clarified issues surrounding the use of a gatekeeper for accessing personal data on participants, as well as issues surrounding consent and the associated information to participants [6]. We covered other issues including, breaches of confidentiality, use of personal identifiable information, open access data and secondary analysis of data. We also highlighted the important considerations for use of placebos and research involving participant deception.

In this, our new update for 2020 onwards, we provide the following revisions and additions;

- More detail on how to ensure consent/assent is truly informed.
- More detail on issues in secondary data analysis projects, and in particular research using data already collected from athletes as part of their contractual obligations with club and/or country.
- More detail on factors to consider when undertaking pre-study risk analysis and in study design.
- Information on the application of the *Principle of Justice*[7]; with particular regard to gender imbalance in sampling.
- Minor text changes to correct typographic errors and to clarify statements carried forward from previous versions.
- Minor changes to the order and layout to enhance readability and usability and reduce areas of overlap.

Research Involving Human Participants

All submitting authors should confirm that research involving human participants has been conducted ethically according to the principles of the World Medical Association Declaration of Helsinki

[8]. The Declaration is intended to be read as a whole and every principle is equally important. Those aspects of ethics, most pertinent to the types of research undertaken by sport and exercise scientists, are highlighted below:

1. **Basic principles.** Respect for the dignity, rights, safety and well-being of all actual and potential participants, researchers, non-participating members of the public, and the environment takes precedence over scientific, or any other, considerations or interests.
2. **Ethical review.** Before any substantive work begins (and before any amendments are made - after ethical approval), the research must be reviewed and approved by the relevant Research Ethics Committee/Institute Review Board (REC/IRB). N.B. Since the primary purpose of ethical review is to protect the participants, ethical approval cannot be granted retrospectively.
3. **Protocol.** All aspects of the methods must be described clearly and be justifiable and appropriate. In writing the study protocol, the researcher must consider;
   a) ethical issues (with the Declaration of Helsinki as the principle reference),
   b) potential conflicts of interest and disclosure of any funding and sponsorship arrangements, institutional affiliations, and any other potential sources of conflict,
   c) the contribution of the work to the knowledge base in the area under study,
   d) arrangements for indemnifying participants, including compensation for anyone harmed as a result of participation,
   e) arrangements for treatment (or support), both immediate and in the longer term, for anyone injured or harmed as a result of participation. N.B. Researchers are not expected to provide treatment themselves (emergency First Aid/Responder type actions notwithstanding). Rather participants should be advised to seek help from their usual medical provider,
   f) arrangements for post-study access - by all participants - to interventions identified as beneficial in the study or access to other appropriate care or benefits.
4. **Consent.** The potential participant's choice (about participation) should be fully informed, free and private. Informed consent/assent should be recorded in writing - Justification should be given for any exceptions to this. Where consent/assent is oral, how and when that consent was given should still be formally documented and witnessed. Research that involves very young people, or others who are unable to consent (e. g. vulnerable adults), should involve consultation with an appropriate person and the assent of the participant (wherever the latter is possible). Research involving participants who are known to lack the mental capacity to give an informed consent may be undertaken only in accordance with local statute, e. g. [9, 10]. In addition to all other considerations, the baseline principle that - having the characteristics, that impair informed consent, is a crucial aspect of eligibility (and hence, the research aims could not be achieved, with recruitment from any other population) - is expected to have been met.
5. **Information,** for consent/assent, must be presented in accessible language/format and encompass (as a minimum) the;
   a) researcher's names and institutional affiliations
   b) aims of the research (i. e. why the work is being undertake),
   c) methods (i. e. what participants will be asked to do),
   d) sources of funding
   e) conflicts of interest
   f) anticipated benefits and potential risks
   g) potential discomfort
   h) right to decline the invitation to participate - without consequence
   i) the right to withdraw consent - without consequence - after consent but before data collection is completed
   j) the right to withdraw data after collection (if applicable)
   k) arrangements for data storage, sharing, retention/destruction etc.
   l) contact details for questions and/or complaints
6. **Conduct.** Research must be conducted;
   a) in accordance with appropriate risk management (as identified in the pre-study risk assessment)
   b) by appropriately qualified researchers and support staff
   c) with skill and care
   d) in an appropriate setting
   e) in a way that protects the privacy of participants and the confidentiality of their personal information
   f) in accordance with applicable statute and frameworks/regulations of the country (or countries) in which the research is to be performed as well as international norms and standards. NB Country, or region, specific statute and frameworks/regulations often cover: aspects of research ethics; the collection, use and/or storage of human tissue; the protection of individuals that lack the capacity to consent; data access, processing and protection; and the use of drugs in research etc.
7. **Governance.** Serious adverse events/reactions, occurring during the research, must be reported to the approving REC/IRB and the Sponsor in a timely period.
8. **Use of social media.** All research which involves the use of social media to recruit participants, conduct research or as a data source must: be ethically reviewed and approved by an appropriate ethics committee, ensure that the principles of informed consent; risks, burdens and benefits; and privacy and confidentiality are adhered to. Researchers should address the following issues; the practicalities of providing information, recording consent and collecting/using data; anonymity, privacy and confidentiality in a setting whereby information is publicly available from identifiable sources; the potential for harm and intrusion; data ownership and security; researcher identity.
9. **Pertinent and incidental findings.** Pertinent findings are related to the variable or primary outcome(s) being studied and incidental findings are not related to the variable or primary outcome(s) being studied. Pertinent and incidental findings may be interesting or important to research participants and it is the responsibility of researchers to decide whether to feedback findings, to provide clear information to participants on their intentions, seek consent, respect autonomy and understand and manage expectations by having a practical feedback pathway that is adequately resourced and approved by the relevant IRB/REC.
10. **Participant involvement.** In accordance with recommendations made by the Nuffield Council on Bioethics to the Health Research

Authority [11], researchers should endeavour to involve children, young people and parents/guardians, as appropriate, in the design of research. Participant involvement in other aspects of the research such as the dissemination of findings is also good practice. Authors may conduct their research in accordance with principles detailed by professional associations and sources other than the World Medical Association Declaration of Helsinki such as the International Sociological Association's (ISA) Code of Ethics [12]. It is recognised that differences in ethical principles may exist between professional associations and sources, e. g.:

a) The ISA's code of Ethics states that "The consent of research subjects and informants should be obtained in advance. Covert research should be avoided in principle, unless it is the only method by which information can be gathered, and/or when access to the usual sources of information is obstructed by those in power." [12].
b) The UK Medical Research Council has outlined some basic principles of good research practice which may help to ensure that research is conducted ethically. These include planning, conduct, recording data, reporting and applying results [13].
c) Relevant issues, not specifically raised in the Declaration of Helsinki include, for example: the use, calibration and maintenance of equipment, adherence to Control of Substances Hazardous to Health Regulations (and local/National equivalents), documentation of standard operating procedures, retention of data, publication policy, authorship, correction of errors and retraction of published findings and intellectual property rights. Authors are required to detail and justify, where aspects of their research abide by ethical principles set down by professional associations or sources that differ, in substance, from any of the principles in the Declaration of Helsinki, or this editorial.

Author Obligations

By reading and citing this editorial, the author(s) confirm the following points are upheld [14]:

1. The points, principles and practice guidance, contained in this editorial were considered and have been adhered to (the statement required under 1.10 c), above, notwithstanding).
2. That consent/assent, to participate was valid, in that potential participants were provided with adequate information, consent/assent was given voluntarily and that those providing consent/assent were competent to do so.
3. Where research involved participants who were vulnerable or unable to provide consent, authors must confirm that the participants were appropriately identified, approached and recruited, there was justification for carrying out the research with these individuals and additional measures were put in place to ensure the research was ethical and complied with applicable statute.
4. Issues of privacy and confidentiality were considered carefully, as matters of ethics and not only to meet any minimum legal requirements. Where, "privacy is the protection of control over information about oneself; control over access to oneself, both physically and mentally; and control over one's ability to make important decisions about family and lifestyle in order to be self-expressive and to develop varied relationships" [14]. And confidentiality is when the "participant discloses to the researcher information which the participant regards as confidential or secret [default assumption]; and the researcher undertakes (implicitly or explicitly) not to reveal this information to anyone who does not already possess it." [14].
5. Researchers considered their own and the Sponsor's, legal and ethical obligations if privacy and confidentiality are breached.
6. If the confidential information that was provided as part of a research study has (or will be) accessed and processed for any other purposes, that confidentiality has been preserved by anonymising the information and that consent for that was obtained, or - where derogations allowing access and processing without consent (for example) are applicable - the terms of those were/will be complied with.
7. Risks relating to harm, inconvenience, time and money, as well as any benefits to the participant, to other individuals, to the researchers and organisations were considered in a balanced fashion, communicated to the participants as part of the consent/asent process and appropriately managed.
8. Likely variation in participant's reaction to and experience of, interventions, outcome measures etc., arising from not only their physical and mental abilities, but, all other known determinants (such as gender, age, physical maturity etc.) were considered in all aspects of the design and methods.
9. Participants were not exploited and particular groups were not discriminated from participation.
10. There were appropriate governance arrangements and structures in place if participants were asked to donate biological material for use in future research, such as a "biobank". These arrangements should involve appropriate consideration of broad consent, privacy and confidentiality, feedback to the participant of incidental findings, storage of material, commercial involvement, donor involvement, intellectual property rights and local statute.
11. Participants were informed of and consented/assented to, all aspects of data access and processing; i. e. the storage of data, including how and where the data is stored, the security of storage, how long data are stored for, what uses the data will have, who will have access to the data (other researchers, institution staff, general public) and any data sharing that may occur etc.

Research Involving Animals

Authors who cite this editorial confirm that research involving animals has been conducted ethically according to the principles of the Guide for the Care and Use of Laboratory Animals of the Institute for Laboratory Animal Research [15]. Again, the guide is intended to be read as a whole, but the basic obligations on the researcher are summarised below. The researcher must;

1. Ensure the appropriateness of experimental methods
2. Legally acquire animals
3. Ensure that animals are properly housed and fed to ensure safe, hygienic and comfortable living conditions.
4. Maintain a record of animal care
5. Ensure that animal maintenance and research are carried out by qualified personnel, following all applicable legal statutes and regulations
6. Administer appropriate pain management to minimize suffering, discomfort and pain

The 8th edition of the Guide for the Care and Use of Laboratory Animals [16], published in 2010, includes expanded coverage of the ethics of laboratory animal use; components of effective Animal Care and Use Programmes; and new guidelines for the housing, environment, and enrichment of terrestrial and aquatic animals, and for veterinary and clinical care [17]. Specifically:

- The core foundation of the guide — replacement, refinement, and reduction.
- An Animal Care and Use Programme
- The performance standards approach for animal care and care practices
- The care and use of fish and other aquatic species
- Housing space and enclosures for animals' social needs
- Environmental enrichment for the enhancement of animal well-being to provide sensory and motor stimulation and promote psychological health
- Discussion of animal biosecurity practices

Exercise Protocols in Animal Research

A useful document for any researcher interested in studying animals in an exercise context is the Resource Book of the American Physiological Society [18]. It is clear that the study of animals can help elucidate the mechanisms of exercise–related benefits to both human and animal health. Nevertheless, any animal study that has been specifically designed to answer a research question based solely on the enhancement of human athletic performance should include a clear explanation as to why such a study is necessary, and why it could not be undertaken on humans. This justification is important, not just from an ethical perspective, but is in keeping with the aim of maximising external validity in any study.

Specific Issues Relevant to Sports Medicine and Publishing in the IJSM

1. **Secondary data analysis projects.** Data are routinely collected from individuals for various purposes; e. g. an athlete's physiological function, or health status, may be monitored (and corresponding data recorded) for training purposes. Such data collection may be a contractual obligation for some. Researchers must consider that data collected for one purpose (e. g. performance monitoring), cannot normally be accessed or processed for another purpose (e. g. research) unless explicit and informed, consent for the secondary data access and processing is obtained (and the research ethically approved), or local derogations permitting such access and processing without consent are adhered to. This issue is particularly pertinent (and hence great care must be taken) where the data concerned was collected as part of a contractual obligation. Researchers who are accessing, processing and/or storing data obtained from large accessible repositories should do so according to terms of the repository holder.
2. **The use of placebo.** The inclusion of a placebo group (whether the study involves athletes or not) may challenge the principle of equity and should only occur where there is genuine equipoise regarding the efficacy/effectiveness of the intervention under study. Participants should be randomly assigned, with adequate concealment approaches, to experimental or placebo groups and allocation should be blinded wherever possible. After a finite length of time those participants in the comparator group could be offered the experimental condition, and an experiment should normally be halted if it became clear that the placebo group was fairing more poorly [19]. In research where participants are patients or clients, extreme care must be taken to avoid the abuse of placebo. The use of placebo is generally acceptable only when there is equipoise concerning the intervention under study, any risk of harm is proportionate to the likely benefits and hence no *proven* treatment is withheld.
3. **Deception.** The use of deception in research (e. g. in a pacing strategy study in which time trial distance is deceived) must be minimal and justified:
   a) Minimal; in the majority of studies while the purpose or aim of the study may require to be concealed, what participants will be asked to do, does not, and
   b) Justified, in that no reasonable alternative methods could be used to obtain the data required to achieve the aims. In addition there should not normally be any anticipated pain or emotional distress for participants.
   c) Where there is deception, participants must be accurately informed of the nature, extent and purpose of the deception, as soon as is possible, and given the option to withdraw their data if they wish [20].
4. **Athletes as participants in studies on doping agents.** In principle, recreational and elite athletes should not be recruited to participate in research that exposes them to violations of the World Anti-Doping Code [21]. However, there may be value of research into doping in sport and so a legitimate reason to recruit athletes as participants. Investigators who wish to recruit athletes as participants in research involving performance enhancing substances and methods should consider the following:
   a) Consultation with appropriate and relevant authorities (specific to each individual athlete) such as IRB/RECs, World Anti-Doping Agency (WADA), international sport federations and national anti-doping organisations – to help protect recreational athletes, elite athletes and sport.
   b) An unfair advantage should not be afforded to a recreational or elite athlete participating in the research.
   c) "Adequate precautions should be taken so that the results of research are not misused and applied for doping" [21]
   d) Append the WADA letter entitled "Scientific research using elite athletes: WADA point of view" [22] to the participant information sheet to help fully inform participants who are recreational or elite athletes.

Ethics and Sample Size

Statistical power and precision should be considered by all authors submitting to IJSM. Ideally an *a priori* estimation of the minimal sample size for adequate statistical power and/or adequate precision of a confidence interval should be reported. *Post hoc* statistical power estimations (based on the observed effect size in the study) are now frowned upon. Authors and reviewers of IJSM manuscripts should be aware of the following important points:

1. The minimal sample size for adequate statistical power should be considered alongside the burden of the study procedures on individual participants/animals and the predicted importance of the study findings to the knowledge base as well as to the impact on real-world practice [23]. An unethical scenario is where many participants or animals have been substantially burdened by the study procedures, but the study findings have dubious clinical/practical importance. A "small" study might not be unethical, especially if participant burden is low and clinical/practical importance of the study findings are high, even if "statistical significance" has not been realised.
2. For the importance of a study to be judged, it is imperative that the minimal clinically/practically important magnitude of change or difference is rationalised clearly and reported by authors [24]. We encourage authors to report the associated confidence interval(s), at least for the primary study outcomes. Authors who rely solely on statistical significance (i. e. the size of a p-value) to judge clinical/practical importance will have their manuscripts rejected. It is important to recognise the difference between the minimal clinically important effect size/association and the minimal detectable effect. The latter is the lowest effect size or association that can be detected with a given precision and sample size whereas the former the the effect size or association that is important clinically/practically on the basis of potential for altering "hard" outcomes like morbidity or mortality.
3. It is wholly inappropriate for a reviewer to criticise a study on the basis of a perceived small sample size without considering the above issues of participant burden and clinical/practical importance. Nevertheless, it is important for researchers to appreciate the possibility that an unusually large sample effect size was observed through the sampling error associated with a small sample size, sometimes referred to as "The Winners Curse" [25].
4. There are useful guidelines on what constitutes a pilot or feasibility study, e. g. [26]. Such studies do not necessarily have to be powered to detect a certain effect size. Alternatively, they may be powered to detect, with adequate precision, a standard deviation for use to ultimately help estimate the required sample size for a substantive trial.

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